FDA 510(k) Premarket Notification

K951705 MINISTRIP HCG

CLEARED

Oct 3, 1995
172 days to decision

K951705 · Product code: **JHI** · Chemistry
Source: https://www.510kdatabase.net/k951705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 14, 1995
Decision date	Oct 3, 1995
Days to decision	172 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**International Newtech Development, Inc.**
Location	Richmond, B.C., CA
Contact	JESSE ZHU
510(k) history	8 submissions · 8 cleared · 1995-2000